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Research and Innovation to Stop E-cigarette/Vaping in Young Adults Consent

ID # GR120236
NCT ID: Not yet assigned
June 28, 2021

The Ohio State University Consent to Participate in Research

Study Title: Research Innovation to Stop e-cigarettes (RISE)

Principal Investigator: Elizabeth Klein, PhD, MPH

Sponsor: American Heart Association

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. This study is designed to evaluate different techniques to help e-cigarette users stop using e-cigarettes (vaping). The study will last about 16 weeks and involve counseling calls from research staff. Participants will be assigned (by chance) to either nicotine replacement products or an on-line program designed to encourage users to stop vaping. The risks of study are considered minimal.

1. Why is this study being done?

You are being asked to take part in this study because you use e-cigarettes and expressed willingness to quit using. The goal of this research is to see how effective other methods may be in helping you stop vaping.

2. How many people will take part in this study?

We will recruit 1200 people to participate in the study.

3. What will happen if I take part in this study?

In the study, you will receive 2 counseling calls from research study coaches. We may contact you at the phone numbers you give us. Note that calls may be automated. Some messages may be pre-recorded. Counseling sessions will last 10-15 minutes. If you do not complete the first study coaching call, then you will be removed from the study, and you will not receive study benefits or services. In addition to the counseling calls, you will be randomly assigned (like flipping a coin) to additional quitting support programs. You may be assigned to receive quit medications (nicotine replacement therapy, NRT) or not. You may be assigned to receive a digital quitting program (explained in the next paragraph) or not. If assigned to receive NRT, an 8-week supply of either nicotine patch, gum, and/or lozenge will be mailed to your address, split over 2 shipments. You will receive your first shipment after your first coaching call and your second shipment only after the second coaching call.

If assigned to receive the digital quitting program, you will receive access to a self-paced online course to support quitting e-cigarettes. You will also receive daily text messages. These text messages are personalized based on information you provide in study surveys and your text message responses. You can opt-out of the text messaging service at any time by replying "STOP" and will not be penalized for doing so. In such a case, you would no longer receive supportive text messages for quitting e-cigarettes, but you will still have access to the online course.

The frequency of texts you receive may vary depending on your usage of the program. Message and data rates may apply and texting terms and conditions may be found **here [hover image text attached in separate document]**. Your agreement to this Consent means that you agree to receive these messages via text and/or email. You will also have the ability to respond via text to certain text messages.

You will be asked to complete an initial survey today, and a follow-up survey at the end of the study period. Each survey will take about 30 minutes. If you become pregnant at any time during the study, you will need to email the Program Manager, Elizabeth Hustead (hustead.7@osu.edu) immediately and you will no longer be eligible to participate in the study.

4. How long will I be in the study?

If you decide to participate, you will be enrolled in the study for up to 16 weeks.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are

otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The risks of the study include discomfort in answering questions about your vaping or health, potential loss of privacy and risks associated with using NRT products. You do not have to answer any questions that you do not want to and can stop a survey at any time.

There are also privacy risks associated with the use of unencrypted email and text message communications that are part of the study. You understand and agree that text messaging and email communications used in the study are not encrypted and that presents a risk of disclosure or interception by third parties. Therefore, please be mindful of your responses and take steps to protect your device.

7. What benefits can I expect from being in the study?

You may benefit from taking part in the study by having an opportunity for support to reduce or stop vaping.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

The study team will make every effort to keep your study-related information confidential. All information will be kept in locked file cabinets and on secured systems. Only study staff will be able to look at your study information. However, because we are using the Internet, there is a chance that someone could access your online responses without permission. Additionally, as described above, email and text message communications are not encrypted and there is some risk of disclosure or interception by a third party. In some cases, this information could be used to identify you. Reports on findings from this study will not use your name and will only report the results as a group.

However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Your records may be reviewed by the following groups:

- Office for Human Research Protections, U.S. Food and Drug Administration
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices

- Study staff at OSU, Optum/Consumer Wellness Solutions Inc., including their affiliated entities and vendors/contractors supporting the study, may have access to your contact and study information.

10. Will my de-identified information be used or shared for future research?

Yes, your de-identified study information may be used or shared with other researchers without your additional informed consent. This means we would not share your name or any information that could identify you. Unless you withdraw your permission to use your health information, there is no date your permission ends. Study information may be analyzed for many years and will be stored indefinitely. It is not possible to know when this will be complete. You may withdraw from the study or take away your permission to use and disclose your health information at any time. If you withdraw your permission, you will not be able to stay in this study. Agreeing to this authorization also means that you may not be able to see or copy your study-related information until the study is completed. If you decide not to give permission to use and give out your health information, then you will not be able to be in this research study. Your de-identified information will not be used or shared for future research.

11. What are the costs of taking part in this study?

There is no cost to you to participate in this study.

12. Will I be paid for taking part in this study?

You will be paid for your time and effort in this study. You will be paid \$40 after you complete the first coaching call, and \$40 to complete the follow-up survey 3 months after your second coaching call. Payments will be automatically distributed in the form of Amazon e-gift cards via the Qualtrics Rewards Genius Integration service at the completion of the t time points listed above. By law, payments to participants are considered taxable income.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Dr. Elizabeth Klein** at **614-292-5424**.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Elizabeth Klein** at **614-292-5424**.

I understand that I will be asked to complete online surveys as a participant in this study.

236 ☐ Yes (1)

237 ☐ No (2)

238

239 I understand that I will be expected to complete two counseling phone sessions with a vaping
240 cessation coach.

241 ☐ Yes (1)

242 ☐ No (2)

243 As a part of this study, I understand that I may receive unencrypted emails and text messages
244 about vaping cessation.

245 ☐ Yes (1)

246 ☐ No (2)

247

248 I understand that I can opt out of this research study at any time.

249 ☐ Yes (1)

250 ☐ No (2)

251

252 **Providing Consent:**

253 I have read (or someone has read to me) this page and I am aware that I am being asked to
254 participate in a research study. I have had the opportunity to ask questions and have had them
255 answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up
256 any legal rights by agreeing to participate.

257 ☐ Yes (1)

258 ☐ No (2)

259

260 To print or save a copy of this page, select the print button on your web browser.

261

262 **Please click the button below to proceed and participate in this study. If you do not wish**
263 **to participate, please close out your browser window.**

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Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of participant

Signature of participant

Date and time

AM/PM

Printed name of person authorized to consent for participant (when applicable)

Signature of person authorized to consent for participant (when applicable)

Date and time

AM/PM

Relationship to the participant

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time

AM/PM

Witness(es) - May be left blank if not required by the IRB

Printed name of witness

Signature of witness

Date and time

AM/PM

Printed name of witness

Signature of witness

Date and time

AM/PM